



1632

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Charles L. Sawyers et al.
Serial No.: 10/022,115
Filed: December 14, 2001
Docket: 30435.53USD2
Title: MICE MODELS OF HUMAN PROSTATE CANCER PROGRESSION

CERTIFICATE UNDER 37 CFR 1.8

I hereby certify that this paper or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on September 26, 2003.

By: 
Name: Richelle Ann Domingo

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Sir:

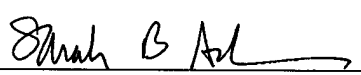
We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing Certificate under 37 CFR 1.8.
- ☒ Information Disclosure Statement (37 C.F.R. §1.97(b)(3))
- ☒ Form 1449 (Information Disclosure Statement)
- ☒ Exhibits 9 – 40
- ☒ Return postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO

55 S. Lake Avenue, Suite 710
Pasadena, California 91101
(626)395-7801

By: 

Name: Sarah B. Adriano
Reg. No.: 34,470
Initials: SBA
Customer No: 26,941




IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Charles L. Sawyers, et al. **Examiner:** Not Yet Known
Serial No.: 10/022,115 **Group Art Unit:** 1632
Filed: December 14, 2001 **Docket No.:** 30435.53USD2
Title: MICE MODELS OF HUMAN PROSTATE CANCER PROGRESSION

CERTIFICATE UNDER 37 CFR 1.8:

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313 on September 26, 2003

By: 
Richele Ann Domingo

55 S. Lake Avenue, Suite 710
Pasadena, California
September 26, 2003

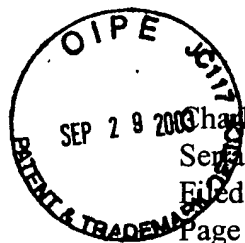
INFORMATION DISCLOSURE STATEMENT
(37 C.F.R. §1.97(b)(3))

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Information Disclosure Statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(d), copies of Exhibits 9-40 as set forth in the Form 1449 are included herewith.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:



- Aldrovandi, Grace M. et al., "The SCID-hu Mouse as a Model for HIV-1 Infection," *Nature*, June 24, 1993, 363:732-6. (Exhibit 9)
- Batson, Oscar V., "The Role of the Vertebral Veins in Metastatic Processes," *Ann. Int. Med.*, 1942, 16:38-45. (Exhibit 10)
- Berrettoni, Beth A. and John R. Carter, "Current Concepts Review Mechanisms of Cancer Metastasis to Bone," *The Journal of Bone and Joint Surgery*, 1986, 68A:308-312. (Exhibit 11)
- Brandt, Burkhard et al., "Isolation of Prostate-Derived Single Cells and Cell Clusters From Human Peripheral Blood," *Cancer Research*, October 15, 1996, 56:4556-61. (Exhibit 12)
- Coman, Dale Rex and Robert P. DeLong, "The Role of the Vertebral Venous System in the Metastasis of Cancer to the Spinal Column," *Cancer*, 1951, 4:610-8. (Exhibit 13)
- Deguchi, T. et al., "Detection of Micrometastatic Prostate Cancer Cells in the Bone Marrow of Patients with Prostate Cancer," *British Journal of Cancer*, 1997, 75(5):634-8. (Exhibit 14)
- Ellis, William J. et al., "Characterization of a Novel Androgen-Sensitive, Prostate-Specific Antigen-Producing Prostatic Carcinoma Xenograft: LuCap 23," *Clinical Cancer Research*, June 1996, 2:1039-48. (Exhibit 15)
- Fidler, Isaiah J., "Critical Factors in the Biology of Human Cancer Metastasis: Twenty-Eight G.H.A Clowes Memorial Award Lecture," *Cancer Research*, October 1, 1990, 50:6130-8. (Exhibit 16)

- Ghossein, Ronald A. et al., "Detection of Circulating Tumor Cells in Patients with Localized and Metastatic Prostatic Carcinoma: Clinical Implications," *Journal of Clinical Oncology*, May 1995, 13(5):1195-200. (Exhibit 17)
- Gleave, Martin E. et al., "Serum Prostate Specific Antigen Levels in Mice Bearing Human Prostate LNCaP Tumors are Determined by Tumor Volume and Endocrine and Growth Factors," *Cancer Research*, March 15, 1992, 52:1598-605. (Exhibit 18)
- Haq, Mahmudul et al., "Rat Prostate Adenocarcinoma Cells Disseminate to Bone and Adhere Preferentially to Bone Marrow-Derived Endothelial Cells," *Cancer Research*, September 1, 1992, 52:4613-9. (Exhibit 19)
- Hsieh, J.T. et al., "An Androgen-Independent Model of Human Prostate Cancer Progression: Molecular and Cellular Characterization," *Proceedings of the American Association for Cancer Research*, March 1993, 34:248. (Exhibit 20)
- Hsu, Su-Ming et al., "A Comparative Study of the Peroxidase-Antiperoxidase Method and an Avidin-Biotin Complex Method for Studying Polypeptide Hormones with Radioimmunoassay Antibodies," *American Society of Clinical Pathologists*, 1981, 75:734-8. (Exhibit 21)
- Karp, Judith E. et al., "Prostate Cancer Prevention: Investigational Approaches and Opportunities," *Cancer Research*, December 15, 1996, 56:5547-56. (Exhibit 22)
- Katz, Aaron E. et al., "Molecular Staging of Prostate Cancer with the Use of an Enhanced Reverse Transcriptase-PCR Assay," *Urology*, June 1994, 43(6):765-75. (Exhibit 23)

- Kjønneksen, Inge et al., "Validity and Usefulness of Human Tumor Models Established by Intratibial Cell Inoculation in Nude Rats," *Cancer Research*, April 1, 1994, 54:1715-9.
(Exhibit 24)
- Kozlowski, James M. et al., "Prostate Cancer and the Invasive Phenotype: Application of New In Vivo and In Vitro Approaches," *Tumor Progression and Metastasis*, 1988, 189-231.
(Exhibit 25)
- Marcelli, Marco et al., "Definition of the Human Androgen Receptor Gene Structure Permits the Identification of Mutations that Cause Androgen Resistance: Premature Termination of the Receptor Protein at Amino Acid Residue 588 Causes Complete Androgen Resistance," *Molecular Endocrinology*, 1990, 909:1105-16. (Exhibit 26)
- Melchior, Sebastian W. et al., "Clinical Relevance of Prostate Cells in the Bone Marrow of Patients with Clinically Localized Carcinoma of the Prostate (CAP)," *The Journal of Urology*, 1997, 157:1718. (Exhibit 27)
- Nagabhushan, Moolky et al., "CWR22: The First Human Prostate Cancer Xenograft with Strongly Androgen-Dependent and Relapsed Strains Both In Vivo and in Soft Agar," *Cancer Research*, July 1, 1996, 56:3042-6. (Exhibit 28)
- Netland, Peter A. and Bruce R. Zetter, "Metastatic Potential of B16 Melanoma Cells after In Vitro Selection for Organ-specific Adherence," *The Journal of Cell Biology*, September 1985, 101:720-4. (Exhibit 29)

- Nishijima, Yukiko et al., "Clinical Significance of the Vertebral Vein in Prostate Cancer Metastasis," *Adv. Exp. Med. Biol.*, 1992, 324:93-100. (Exhibit 30)
- Noel, A. et al., "Basement Membrane Components (Matrigel) Promote the Tumorigenicity of Human Breast Adenocarcinoma MCF7 Cells and Provide an In Vivo Model to Assess the Responsiveness of Cells to Estrogen," *Biochemical Pharmacology*, 1992, 43(6):1263-7. (Exhibit 31)
- Pang, Shen et al., "Prostate Tissue Specificity of the Prostate-Specific Antigen Promoter Isolated from a Patient with Prostate Cancer," *Human Gene Therapy*, November 1995, 6:1417-26. (Exhibit 32)
- Saiki, Randall K. et al., "Enzymatic Amplification of Beta-Globulin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," *Science*, 1985, 230:1350-4. (Exhibit 33)
- Seiden, Michael V. et al., "Detection of Circulating Tumor Cells in Men with Localized Prostate Cancer," *Journal of Clinical Oncology*, December 1994, 12(12):2634-9. (Exhibit 34)
- Sutherland, Richard W. et al., "Androgen Receptor Gene Mutations are Rarely Associated with Isolated Penile Hypospadias," *The Journal of Urology*, 1996, 156:828-31. (Exhibit 35)
- Thalmann, George N. et al., "Androgen-Independent Cancer Progression and Bone Metastasis in the LNCaP Model of Human Prostate Cancer," *Cancer Research*, May 15, 1994, 54:2577-81. (Exhibit 36)

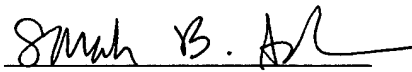
- Wang, Min and Mark E. Stearns, "Isolation and Characterization of PC-3 Human Prostatic Tumor Sublines Which Preferentially Metastasize to Select Organs in S.C.I.D. Mice," *Differentiation*, 1991, 48:115-25. (Exhibit 37)
- Wood, David P. Jr. et al, "Identification of Bone Marrow Micrometastases in Patients with Prostate Cancer," *Cancer*, 1994, 74:2533-40. (Exhibit 38)
- Wu, His-Chin et al., "Derivation of Androgen-Independent Human LNCaP Prostatic Cancer Cell Sublines: Role of Bone Stromal Cells," *Int. J. Cancer*, 1994, 57:406-12. (Exhibit 39)
- Zetter, Bruce R. et al., "The Cellular Basis for Prostate Cancer Metastasis," *Adv. Exp. Med. Biol.*, 1992, 324:39-43. (Exhibit 40)

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that the references have been thoroughly reviewed or that any relevance of any portion of a reference is intended.

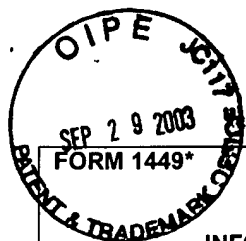
Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-0306.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Sarah B. Adriano", is written over a horizontal line.

Sarah B. Adriano
Registration No. 34,470
Attorney for Applicants
Mandel & Adriano
55 S. Lake Avenue, Suite 710
Pasadena, CA 91101
(626) 395-7801
Customer No. 26,941

**INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number

30435.53USD2

Application Number

10/022,115

Applicant

Charles L. Sawyers et al.

Filing Date

December 14, 2001

Group Art Unit

1632

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Aldrovandi, Grace M. et al., "The SCID-hu Mouse as a Model for HIV-1 Infection," <i>Nature</i> , June 24, 1993, 363:732-6. (Exhibit 9)
	Batson, Oscar V., "The Role of the Vertebral Veins in Metastatic Processes," <i>Ann. Int. Med.</i> , 1942, 16:38-45. (Exhibit 10)
	Berrettoni, Beth A. and John R. Carter, "Current Concepts Review Mechanisms of Cancer Metastasis to Bone," <i>The Journal of Bone and Joint Surgery</i> , 1986, 68A:308-312. (Exhibit 11)
	Brandt, Burkhard et al., "Isolation of Prostate-Derived Single Cells and Cell Clusters From Human Peripheral Blood," <i>Cancer Research</i> , October 15, 1996, 56:4556-61. (Exhibit 12)
	Coman, Dale Rex and Robert P. DeLong, "The Role of the Vertebral Venous System in the Metastasis of Cancer to the Spinal Column," <i>Cancer</i> , 1951, 4:610-8. (Exhibit 13)
	Deguchi, T. et al., "Detection of Micrometastatic Prostate Cancer Cells in the Bone Marrow of Patients with Prostate Cancer," <i>British Journal of Cancer</i> , 1997, 75(5):634-8. (Exhibit 14)
	Ellis, William J. et al., "Characterization of a Novel Androgen-Sensitive, Prostate-Specific Antigen-Producing Prostatic Carcinoma Xenograft: LuCap 23," <i>Clinical Cancer Research</i> , June 1996, 2:1039-48. (Exhibit 15)
	Fidler, Isaiah J., "Critical Factors in the Biology of Human Cancer Metastasis: Twenty-Eight G.H.A. Clowes Memorial Award Lecture," <i>Cancer Research</i> , October 1, 1990, 50:6130-8. (Exhibit 16)
	Ghossein, Ronald A. et al., "Detection of Circulating Tumor Cells in Patients with Localized and Metastatic Prostatic Carcinoma: Clinical Implications," <i>Journal of Clinical Oncology</i> , May 1995, 13(5):1195-200. (Exhibit 17)
	Gleave, Martin E. et al., "Serum Prostate Specific Antigen Levels in Mice Bearing Human Prostate LNCaP Tumors are Determined by Tumor Volume and Endocrine and Growth Factors," <i>Cancer Research</i> , March 15, 1992, 52:1598-605. (Exhibit 18)
	Haq, Mahmudul et al., "Rat Prostate Adenocarcinoma Cells Disseminate to Bone and Adhere Preferentially to Bone Marrow-Derived Endothelial Cells," <i>Cancer Research</i> , September 1, 1992, 52:4613-9. (Exhibit 19)
	Hsieh, J.T. et al., "An Androgen-Independent Model of Human Prostate Cancer Progression: Molecular and Cellular Characterization," <i>Proceedings of the American Association for Cancer Research</i> , March 1993, 34:248. (Exhibit 20)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



FORM 1449

**INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number

30435.53USD2

Application Number

10/022,115

Applicant

Charles L. Sawyers et al.

Filing Date

December 14, 2001

Group Art Unit

1632

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

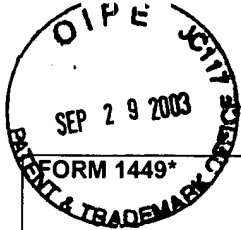
	Hsu, Su-Ming et al., "A Comparative Study of the Peroxidase-Antiperoxidase Method and an Avidin-Biotin Complex Method for Studying Polypeptide Hormones with Radioimmunoassay Antibodies," <i>American Society of Clinical Pathologists</i> , 1981, 75:734-8. (Exhibit 21)
	Karp, Judith E. et al., "Prostate Cancer Prevention: Investigational Approaches and Opportunities," <i>Cancer Research</i> , December 15, 1996, 56:5547-56. (Exhibit 22)
	Katz, Aaron E. et al., "Molecular Staging of Prostate Cancer with the Use of an Enhanced Reverse Transcriptase-PCR Assay," <i>Urology</i> , June 1994, 43(6):765-75. (Exhibit 23)
	Kjønneksen, Inge et al., "Validity and Usefulness of Human Tumor Models Established by Intratibial Cell Inoculation in Nude Rats," <i>Cancer Research</i> , April 1, 1994, 54:1715-9. (Exhibit 24)
	Kozlowski, James M. et al., "Prostate Cancer and the Invasive Phenotype: Application of New In Vivo and In Vitro Approaches," <i>Tumor Progression and Metastasis</i> , 1988, 189-231. (Exhibit 25)
	Marcelli, Marco et al., "Definition of the Human Androgen Receptor Gene Structure Permits the Identification of Mutations that Cause Androgen Resistance: Premature Termination of the Receptor Protein at Amino Acid Residue 588 Causes Complete Androgen Resistance," <i>Molecular Endocrinology</i> , 1990, 909:1105-16. (Exhibit 26)
	Melchior, Sebastian W. et al., "Clinical Relevance of Prostate Cells in the Bone Marrow of Patients with Clinically Localized Carcinoma of the Prostate (CAP)," <i>The Journal of Urology</i> , 1997, 157:1718. (Exhibit 27)
	Nagabhushan, Moolky et al., "CWR22: The First Human Prostate Cancer Xenograft with Strongly Androgen-Dependent and Relapsed Strains Both In Vivo and in Soft Agar," <i>Cancer Research</i> , July 1, 1996, 56:3042-6. (Exhibit 28)
	Netland, Peter A. and Bruce R. Zetter, "Metastatic Potential of B16 Melanoma Cells after In Vitro Selection for Organ-specific Adherence," <i>The Journal of Cell Biology</i> , September 1985, 101:720-4. (Exhibit 29)
	Nishijima, Yukiko et al., "Clinical Significance of the Vertebral Vein in Prostate Cancer Metastasis," <i>Adv. Exp. Med. Biol.</i> , 1992, 324:93-100. (Exhibit 30)
	Noel, A. et al., "Basement Membrane Components (Matrigel) Promote the Tumorigenicity of Human Breast Adenocarcinoma MCF7 Cells and Provide an In Vivo Model to Assess the Responsiveness of Cells to Estrogen," <i>Biochemical Pharmacology</i> , 1992, 43(6):1263-7. (Exhibit 31)
	Pang, Shen et al., "Prostate Tissue Specificity of the Prostate-Specific Antigen Promoter Isolated from a Patient with Prostate Cancer," <i>Human Gene Therapy</i> , November 1995, 6:1417-26. (Exhibit 32)
	Saiki, Randall K. et al., "Enzymatic Amplification of Beta-Globulin Genomic Sequences and Restriction Site Analysis for Diagnosis of Sickle Cell Anemia," <i>Science</i> , 1985, 230:1350-4. (Exhibit 33)
	Seiden, Michael V. et al., "Detection of Circulating Tumor Cells in Men with Localized Prostate Cancer," <i>Journal of Clinical Oncology</i> , December 1994, 12(12):2634-9. (Exhibit 34)
	Sutherland, Richard W. et al., "Androgen Receptor Gene Mutations are Rarely Associated with Isolated Penile Hypospadias," <i>The Journal of Urology</i> , 1996, 156:828-31. (Exhibit 35)
	Thalmann, George N. et al., "Androgen-Independent Cancer Progression and Bone Metastasis in the LNCaP Model of Human Prostate Cancer," <i>Cancer Research</i> , May 15, 1994, 54:2577-81. (Exhibit 36)
	Wang, Min and Mark E. Stearns, "Isolation and Characterization of PC-3 Human Prostatic Tumor Sublines Which Preferentially Metastasize to Select Organs in S.C.I.D. Mice," <i>Differentiation</i> , 1991, 48:115-25. (Exhibit 37)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

**INFORMATION DISCLOSURE STATEMENT
IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number

30435.53USD2

Application Number

10/022,115

Applicant

Charles L. Sawyers et al.

Filing Date

December 14, 2001

Group Art Unit

1632

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)Wood, David P. Jr. et al., "Identification of Bone Marrow Micrometastases in Patients with Prostate Cancer," *Cancer*, 1994, 74:2533-40. (Exhibit 38)Wu, His-Chin et al., "Derivation of Androgen-Independent Human LNCaP Prostatic Cancer Cell Sublines: Role of Bone Stromal Cells," *Int. J. Cancer*, 1994, 57:406-12. (Exhibit 39)Zetter, Bruce R. et al., "The Cellular Basis for Prostate Cancer Metastasis," *Adv. Exp. Med. Biol.*, 1992, 324:39-43. (Exhibit 40)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE